

REMARKS

In accordance with the above amendments, claims 1-2, 5-6, 9, 11-16 and 18 have been amended. Claims 7-8 have been cancelled and new claim 19 has been added. Thus, claims 1-6 and 9-19 remain under consideration. The title to the Abstract of the Disclosure has been corrected.

The detailed action will next be considered.

Specification.

A corrected Abstract of the Disclosure title has been provided to correct a spelling error indicated by the Examiner.

The Examiner has raised certain issues with respect to the specification in regard to claims 15, 16 and 18. While the applicants do not agree that the claim language was unsupported in the specification, these claims have been amended and, it is believed, the amendments render these issues moot.

Drawings.

It is noted that the Examiner has objected to Figures 2, 3 and 9 as failing to comply with 37 CFR 1.84(1) because they are not adequate to permit satisfactory reproduction characteristics. Accordingly, replacement figures 2, 3 and 9 are being supplied with this Response. Reference character 46 has been corrected in Figure 2.

With respect to Item 2, the missing reference characters have been added to Figures 5 and 6. Replacement figure pages are also

being supplied with these corrected figures.

With respect to Figure 7, it is believed that the columns designated 102 and 104 are sufficiently similar that the same reference characters can be used.

It is noted that Figure 8 has also been objected to under 37 CFR 1.84 because columns and rows were unlabeled. Accordingly, a replacement Figure 8 is also provided including necessary labels.

Thus, considering the replacement drawings sheets (Figures 2-9) and the amendments to claims 15, 16 and 18, it is believed that all the objections to the drawings have been properly met and consideration and approval of the drawings including the replacement drawing sheets is respectfully requested. No new matter has been entered.

Claim Objections.

It is believed that the extensive amendments to the claims have corrected each of the enumerated objections raised by the Examiner in the detailed action. In addition, certain other inconsistencies and the like have also been remedied by the amendments. It is now believed that all the objections to the claims have been met.

Claims Rejections - 35 USC § 112.

The Examiner has made several enumerated rejections based on 35 USC § 112. These will be addressed.

Claim 14 has been made dependent upon claim 1 to correct a

raised shortcoming.

Claims 15 and 16 were rejected for reciting the limitation "a common set of equipment" in line 1. It should be noted that this language merely meant that the same equipment could be utilized to acquire all of the necessary data. Even so, the word "common" has been amended to "single" to avoid any misinterpretation. Such equipment is well known to those skilled in the art and it is believed unnecessary to provide further definition in the claim. The equipment is referenced below.

In claim 18, "end-tidal CO₂ analyzer" in line 2 has been amended to "end-tidal CO₂ analysis" thereby no longer reciting a particular piece of equipment.

The data gathering aspect of the invention together with the equipment involved is described beginning at page 8, line 19 through page 9, line 30. These devices are sufficiently well-known, applicants believe, that one skilled in the art can easily practice the measuring and data-gathering aspect of the invention.

Claim Rejection - 35 USC § 102.

It is noted that claims 1-8, 14, 15 and 18 stand rejected under 35 USC § 102(b) as being anticipated by Binder (USPN 6,174,289). This rejection is respectfully traversed. First, it should be noted that claims 7 and 8 have been canceled, and the intended use phrase has been removed from claim 14. In addition, specific delay optimizations have been added to claim 15.

Binder '289 (Binder) describes a gas analysis apparatus and a method for calibrating it for compensating measurement errors.

While the technique described in that reference may be suitable for use during cardiopulmonary exercise, the reference nowhere teaches or suggests using data measured by the gas analysis apparatus to adjust pacing parameters, let alone teaching anything regarding AV or VV delay optimizations. Use of the measurements made within the scope of the present invention assumes that measurement apparatus is, in fact, acquiring accurate data. The present invention has nothing to do with compensating or correcting the equipment.

Therefore, it is submitted that not only does the reference not teach the method of the present invention, it would not even be consulted by one attempting to adjust pacing parameters, which the amended claims clearly require. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

In addition, claims 1-8, 14, 15 and 18 have been rejected under 35 USC § 102(b) as being anticipated by Anderson et al (USPN 4,463,764). This rejection is also respectfully traversed.

Anderson et al '764 (Anderson) describes a method for measuring cardiopulmonary variables on a breath-by-breath basis. While it involves acquisition, analysis, display and printing of an individual's physiological parameters, that reference, like Binder, does not teach or suggest using the data or how to use the data to adjust pacing parameters. The Anderson of the reference is, of course, the same Anderson who is a co-inventor in the present

application.

It should be noted that in the case of both of the above-cited references, that the present invention is not directed to acquiring data of the selected variables *per se*, but to a unique way of utilizing the data representing certain variables to adjust selected pacing parameters including AV and VV delay settings.

Claim Rejection - 35 USC § 103.

It is noted that claims 9-11, 16 and 17 are rejected under 35 USC § 103(a) as being unpatentable over Binder as applied to claim 6 and further in view of Tockman et al (USPN 5,540,727). Claims 9-11, 16 and 17 are also rejected under 35 USC § 103(a) as being unpatentable over Anderson further in view of Tockman et al '727 (Tockman). Both of these rejections are respectfully traversed.

Whereas Tockman discloses using a microprocessor-based controller to automatically optimize pacing mode and/or one or more pacing cycle parameters in an effort to achieve optimization of a cardiac performance parameter, important differences exist between that patent and the present invention.

Tockman '727 uses "cardiac performance parameters", including:

- (a) Cardiac Output - those skilled in the art will recognize that cardiac output = 1/minute of blood flow; measured by CO sensor;
- (b) Respiratory activity = respiratory rate = breaths per minute; measured by accelerometer; and

(c) Respiratory sensor = pO_2 and pCO_2 – partial pressure of respiratory gases in patient's blood (column 2, lines 25 and 26).

On the other hand, the present invention uses "cardiopulmonary parameters", as listed in Definition of Terms, pages 2-4. These are clearly different from the cardiac performance parameters used in Tockman, and anyone skilled in the art would recognize the difference. Thus, Tockman uses heart only data, not heart and lung data. Consequently, the Examiner's statement that "Tockman teaches associating unique values of AV or VV delay with cardiopulmonary variables" is not supported by the reference. In fact, there is no mention of VV delay at all in Tockman.

It is of considerable importance in determining optimal values for AV and VV delay that cardiopulmonary parameters be used rather than cardiac performance parameters. This is because changes in AV and VV delay "have the effect of changing the ventricular filling and stroke output of the heart that, in turn, alters the ventilation-perfusion coupling" (page 8, lines 9-11). In clinical studies using applicant's methodology, the optimal value for AV and VV delay will often require a compromise between the setting that produces the optimal value for stroke output and the optimum value for AV or VV delay using "cardiac performance parameters" alone is not sufficient, since the effects on ventilation are unknown. It should also be noted that any analysis of blood gases (pO_2 , pCO_2 or oxygen saturation) will fail to provide the sensitivity to changes

in AV or VV delay because of the long and/or unknown delay times in producing a change in any of these parameters.

In addition, the claims of the present application clearly state that cardiopulmonary parameters must be measured during exercise. Although not specifically stated, it can be assumed that Tockman's methods use resting measurements, since the listed external sensors (MAP, CO, Respiratory) would have difficulty making these measurements (cardiac performance) during exercise. Exercise is of considerable importance in determining optimal values for AV and VV delay, and it is necessary that the patient perform light exercise (page 5, lines 17-19). It is well known by those skilled in the art that the body performs differently during rest and exercise. Also, any method that relies on any resting measurement is deficient, since patients rarely complain of shortness of breath at rest. Applicant's method is superior in that measurements are made under the conditions of activities of daily living.

The present applicants believe that the current application discloses a novel mathematical method, as in claims 12 and 13, for determining the optimal choice of AV and VV delay that provides the best physiologic performance for both heart and lung parameters. As previously noted, the AV/VV value that provides the best cardiac performance is often not the same AV/VV value that provides the best pulmonary performance. In the current application, commonly available technologies have been combined (cardiopulmonary

measurements, pacemakers with programmable AV and VV delays, incremental step changes in an independent variable) in a new and novel way to produce a beneficial result.

Thus, applicants believe their claims to be clearly patentably distinct from either combination of reference and reconsideration and withdrawal of these rejections are respectfully requested.

In view of the above amendments taken together with the remarks herein, applicants believe all the claims are now in condition for allowance and reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of August 30, 2006, replacement drawing sheets, a Petition for a one-month extension of time, a check in the amount of \$60.00 and a Transmittal Letter in application Serial No. 10/797,948, filed on March 11, 2004, of Stephen T. Anderson et al, entitled "METHOD OF OPTIMIZATION PATIENT OUTCOME FROM CARDIAC RESYNCHRONIZATION THERAPY", are being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on January 3, 2007.

Barbara L. Davis

Barbara L. Davis
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Date of Signature: January 3, 2007